JUN - 2 2000

K001017

SUMMARY OF SAFETY AND EFFECTIVENESS
Retrax Safety Systems, Inc.
The Retrax™ Retracting Needle Syringe

SUBMITTER INFORMATION

A.	Company Name:	Retrax Safety Systems, Inc
B.	Company Address:	1200 Brickell Avenue, Suite 1480
C.	Telephone:	(305) 371-8166
D.	Contact Person:	David M.Garvin President, Chief Executive Officer
E.	Date Prepared:	March 27, 2000

DEVICE IDENTIFICATION

A.	Generic Device Name:	Safety Syringe
B.	Trade/Proprietary Name:	Retrax Retracting Needle Syringe
C.	Classification Name:	Anti-Stick Piston Syringe (880.5860)
D.	Device Class & Panel:	Class II, Panel 80
E.	Product Code:	MEG

DEVICE DESCRIPTION

The Retrax™ Retracting Needle Syringe is a sterile, single-use hypodermic piston syringe intended for intramuscular and subcutaneous injection of medication into a patient, while minimizing the potential for accidental injury as a result of needle sticks (sharps injury). The device incorporates a needle retracting mechanism, which is activated by continuing to depress the plunger after the injection has been completed. Activation may be done while the needle is still in the patient or as soon as practical after the needle is withdrawn from the patient.

The Retrax™ Retracting Needle Syringe is available in a size of 3cc, and a sterile 21-gauge needle, 1 inch in length is provided with the syringe. Retrax offers separate sterile needles, which easily screw onto the Retrax syringe in gauges ranging from 19 to 25 with lengths ranging from 1.5 inches to 5/8 inches. Only needles supplied by Retrax can be used with the Retrax Retracting Needle Syringe

The plunger component is inserted into the fluid containment chamber for pressurizing and directing the fluid through the fluid ports and out to the needle. After all the fluid has been injected, the plunger comes into contact with the forward end of the inner barrel and pushes the anterior end of the inner barrel forward. This forward movement expands the collet fingers and triggers the release of the retracting holder assembly (needle attached), which springs backwards into the inner barrel so that the needle is completely within the syringe. The syringe may then be disposed of in accordance with hospital procedures

INTENDED USE

The Retrax™ Retracting Needle Syringe is indicated for intramuscular and subcutaneous use in the injection of medication into a patient. The Retrax™ Retracting Needle Syringe incorporates a retractable needle safety mechanism that is activated by the user to minimize needle stick injuries after the injection has been completed while the needle is still in the patient or as soon as practical after the needle has been removed from the patient.

SUBSTANTIAL EQUIVALENCE

The Retrax™ Retracting Needle Syringe is substantially equivalent to the VanishPoint® Syringe (formerly the Pop-N-Lock Syringe), which was cleared for commercial distribution under 510(k) K946219 on December 28, 1995.

Retrax™ Retracting Needle Syringe has the same technological characteristics as the VanishPoint® Syringe. Both devices are used to inject medication into a patient, and include a user-activated feature to retract the needle into the syringe barrel after use. Differences that exist between these systems (e.g., physical appearance) do not affect the relative safety or effectiveness of the devices.

PERFORMANCE DATA

Performance data indicate that the Retrax™ Retracting Needle Syringe is substantially equivalent to the VanishPoint® Syringe. There are no performance standards established

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2000

Mr. David Garvin
President, Chief Executive Officer
Retrax Safety Systems, Incorporated
1200 Brickell Avenue, Suite 1480
Miami, Florida 33131

Re: K001017
Trade Name: Retrax Retracting Needle Syringe, Size 3cc
Regulatory Class: II
Product Code: MEG
Dated: March 27, 2000
Received: March 29, 2000

Dear Mr. Garvin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: _____ (To be assigned by FDA)

Device Name: Retrax™ Retracting Needle Syringe

Indications For Use: The Retrax™ Retracting Needle Syringe is indicated for intramuscular and subcutaneous use in the injection of medication into a patient. The Retrax™ Retracting Needle Syringe incorporates a retractable needle safety mechanism that is activated by the user to minimize needle stick injuries after the injection has been completed while the needle is still in the patient or as soon as practical after the needle has been removed from the patient.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDLED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over – The - Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001017